The Claims

1. A method for ffecting an augmented SD treatment of biological products, comprising the steps of:

(a) mixing into the products, SD treatment chemicals following predefined protocol for the use thereof;

(b) mixing into the products one or more ingredient selected from a group of ingredients consisting of formaldehyde and phenol such that final amounts of each added ingredient is a prequalified concentration;

(c) incubating a resulting mixture containing the SD treatment chemicals at a first predetermined temperature for a first predetermined period of time

(d) incubating a resulting mixture containing the ingredients at a second predetermined temperature for a second predetermined period of time;

(e) separating the treated product from the SD treatment chemicals. and

(f) separating the treated product from the one or more ingredients.

2. The method according to Claim 1 wherein the first predetermined temperature is maintained within a range not less than 15 degrees C and not great r than 45 degrees C.

3. The method according to Claim 1 wherein the second predetermined temperature is maintained within a range not less than 15 degrees C and not greater than 45 degrees C.

4. The method according to Claim 1 wherein the first predetermined temperature and the second predetermined temperature are the same temperature.

5. The method according to Claim 1 wherein the first predetermined period of time is not less than one hour and not greater than twelve hours.

6. The method according to Claim 1 wherein the second predetermined period of time is not less than one hour and not greater than twelve hours.

7. The method according to Claim 1 wherein step(a) is performed separately and at a different time than step (b).

8. The method according to Claim 7 wherein step(a) is performed separately and before step (b).

9. The method according to Claim 7 wherein step(a) is performed separately and after step (b).

10. The method according to Claim 1 wherein step(a) is performed concurrently with step (b).

11. The method according to Claim 1 wherein step(e) is performed separately and at a different time than step (f).

12. The method according to Claim 11 wherein step(e) is performed separately and before step (f).

13. The method according to Claim 11 wherein step(e) is performed separately and after step (f).

14. The method according to Claim 1 wherein step(e) is performed concurrently with step (f).

15. The method according to Claim 1 wherein the mixing step comprises products mixed to achieve a final concentration which is in the range of 100 to 10,000 ppm.

16. A process for augmenting a solvent detergent blood plasma treatment, said process comprising the steps of selecting a predetermined solvent detergent to be augmented by added ingredients; selecting one or more of the ingredients to be added from a group of ingredients consisting of formaldehyde, phenol and mixtures of formaldehyde and phenol; simultaneously adding the ingredients with the solvent detergent to a plasma process intermediate-to-be-treated such that the final concentration of each added ingredient from the group of ingredients is from about 100 to 10,000 parts per million; incubating said mixture for a predetermined time at a predetermined temperature; and thereafter separating the treated process intermediate from the treatment solvent detergent and other added ingredients.

17. The process according to Claim 16 wherein the predetermined time is not less than one hour and not greater than twelve hours.

18. The process according to Claim 16 wherein the predetermined temperature is not less than 15 degrees C and not greater than 45 degrees C.

19. A process for augmenting a solvent detergent treatment of a blood plasma process intermediate comprising the steps of selecting a predetermined solvent detergent treatment product for that intermediate; selecting one or more ingredients from a group of ingredients consisting of formaldehyde, phenol and mixtures of formaldehyde and phenol; adding the selected ingredients to the process intermediate such that the final concentration of each added ingredient is from about 100 to 10,000 parts per million; adding, as a next step, an amount of the selected solvent detergent treatment necessary to effect the solvent detergent treatment of the process intermediate; incubating said mixture for a predetermined time and at a predetermined temperature; separating the ingredients and solvent detergent treatment chemicals from the process intermediate to thereby recover the recovery of the desired therapeutic product.

20. The process according to Claim 19 wherein the predetermined time is not less than one hour and not greater than twelve hours.

21. The process according to Claim 19 wherein the predetermined temperature is not less than 15 degrees C and not greater than 45 degrees C.

22. A process for augmenting a solvent d tergent treatment of a blood plasma process intermediate comprising the steps of selecting a predetermined solvent detergent treatment product for that intermediate; selecting one or more ingredients from a group of ingredients consisting of formaldehyde, phenol and mixtures of formaldehyde and phenol; adding, an amount of the selected solvent detergent treatment necessary to effect the solvent detergent treatment of the process intermediate; adding, as a next step, the selected ingredients to the process intermediate such that the final concentration of each added ingredient is from about 100 to 10,000 parts per million; incubating said mixture for a predetermined time and at a predetermined temperature; separating the ingredients and solvent detergent treatment chemicals from the process intermediate to thereby recover the recovery of the desired therapeutic product.

23. The process according to Claim 22 wherein the predetermined time is not less than one hour and not greater than twelve hours.

24. The process according to Claim 22 wherein the predetermined temperature is not less than 15 degrees C and not greater than 45 degrees C.

25. A process for augmenting solvent detergent treatment of a blood plasma process intermediate comprising the steps of selecting a predetermined solvent detergent treatment product for that intermediate; selecting one or more ingredients from a group of ingredients consisting of formaldehyde, phenol and mixtures of formaldehyde and phenol; adding the selected ingredients to the process intermediate such that the final concentration of each added ingredient is from about 100 to 10,000 parts per million; incubating the resulting mixture for a first predetermined time at a first predetermined temperature; separating out the added ingredients to recover the desired partially processed process intermediate; adding the selected solvent detergent treatment product necessary to effect the solvent detergent treatment of the recovered process intermediate; incubating said mixture for a second predetermined time at a second predetermined temperature; and separating out the treatment chemicals, thereby recovering the desired therapeutic product.

26. The process according to Claim 25 wherein the first predetermined time is not less than one hour and not greater than twelve hours.

27. The process according to Claim 25 wherein the first predetermined temperature is not less than 15 degrees C and not greater than 45 degrees C.

28. The process according to Claim 25 wherein the second predetermined time is not less than one hour and not great r than twelve hours.

29. The process according to Claim 25 wherein the second predetermined temperature is not less than 15 degrees C and not greater than 45 degrees C.

30. A process for augmenting a blood plasma process intermediate solvent detergent treatment comprising the steps of selecting a solvent detergent treatment product for the purpose of treating a process intermediate; adding to the process intermediate, the selected solvent detergent treatment product; incubating said mixture for a first predetermined time at a fist predetermined temperature; separating out the treatment chemicals, thereby, recovering a partially processed desired therapeutic product; selecting one or more ingredients from a group of ingredients consisting of formaldehyde, phenol and mixtures thereof; adding the ingredients to the partially processed therapeutic product such that the final concentration of each added ingredient is at a concentration from about 100 to 10,000 parts per million; incubating said mixture for a second predetermined time at a second predetermined temperature; and, thereafter, separating the treating ingredients from the processed process intermediate to thereby recover a desired therapeutic product.

31. The process according to Claim 30 wherein the first predetermined time is not less than one hour and not greater than twelve hours.

32. The process according to Claim 30 wherein the first predetermined temperature is not less than 15 degrees C and not greater than 45 degrees C.

33. The process according to Claim 30 wherein the second predetermined time is not less than one hour and not greater than twelve hours.

34. The process according to Claim 30 wherein the second predetermined temperature is not less than 15 degrees C and not greater than 45 degrees C.

35. An immunoglobulin preparation for use in humans or animals prepared by a process comprising the steps of mixing into an initial process intermediate, SD treatment chemicals following predefined protocol for the use thereof; further mixing into the preparation one or more ingredient selected from a group of ingredients consisting of formaldehyde and phenol such that final concentration of each added ingredient ranges from about 100 to 10,000 parts per million; incubating the resulting mixture containing the SD treatment chemicals and ingredients at a predetermined temperature for a predetermined period of time; separating the treated product from the SD treatment chemicals and the one or more ingredients to thereby provide the desired immunoglobulin preparation.

36. An immunoglobulin preparation for use in humans or animals prepared by a process comprising inactivated enveloped and non-enveloped viruses resulting from mixing and incubating a raw form of the immunoglobulin preparation with SD treatment chemicals following predefined protocol for the use thereof; further mixing into the raw preparation one or more ingredients selected from a group of ingredients consisting of formaldehyde and phenol such that final concentration of each added ingredient ranges from about 100 to 10,000 parts per million; incubating the resulting mixture containing the SD treatment chemicals and ingredients at a predetermined temperature for a predetermined period of time; separating the treated product from the SD treatment chemicals and the one or more ingredients to thereby provide the desired immunoglobulin preparation